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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,654	04/18/2000	James T Loch III	3525-74	8308
22466	7590	06/14/2002		
ASTRA ZENECA PHARMACEUTICALS LP GLOBAL INTELLECTUAL PROPERTY 1800 CONCORD PIKE WILMINGTON, DE 19850-5437			EXAMINER	
			WRIGHT, SONYA N	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 06/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/529,654	LOCH III ET AL.
	Examiner Sonya Wright	Art Unit 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 25-41 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3, 6, 8-24, 42 and 43 is/are rejected.
- 7) Claim(s) 4,5 and 7 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-43 are pending in this office action. Claims 25-40 and 41 are withdrawn from consideration for being drawn to non-elected subject matter.

It is noted that Applicant asked that claims 25-50 inclusive be canceled in the amendment filed 4-22-02 in paper number 8. This amendment has not been entered because there are not 50 claims in the case; there are only 43. It is requested that Applicant file another amendment requesting that the non-elected claims be canceled.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-24, 42, and 43 in Paper No. 8 filed 4-22-02 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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1-3, 6, 8-24, 32

Claims 1-24, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,110,914, Phillips et al., which is a 371 of WO 9903859 (PCT/SE98/01364). Phillips et al. disclose spiroazabicyclic heterocyclic compounds which are useful in the treatment of disorders involving reduced cholinergic function such as Alzheimer's disease. Phillips et al. disclose examples of the instant compounds in a CAS ONLINE structure display. See answer 1, RN 220141-43-5; answer 15, RN 220100-73-2; answer 27, RN 220100-57-2; and answer 45, RN 220100-36-7 in WO 9903859 from a CAS ONLINE structure display. Phillips et al. disclose the instant claims when, in the instant claims R is hydrogen or C1-C4 alkyl; R1 is (CH₂)_nAr, and CH₂CH=CHAr; R2 is absent; and n, A, and Ar are as defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

1-3, 6, 8-24

Claims ~~1-24~~, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,110,914, Phillips et al., which is a 371 of WO 9903859 (PCT/SE98/01364). Applicant discloses substituted amines of spirofuropyridines useful in treating disorders involving reduced cholinergic function such as Alzheimer's disease.

Determination of the scope and content of the prior art (MPEP §2141.01)

Phillips et al. disclose spiroazabicyclic heterocyclic compounds which are useful in the treatment of disorders involving reduced cholinergic function such as Alzheimer's disease. Phillips et al. generically disclose the instant compounds in column 1, lines 45-67 and column 2, lines 1-27. Phillips et al. generically teach claim 42 in col. 5-6, compound IIA in view of col. 15, compound XIX and col. 16, compound II. Phillips et al. disclose examples of the instant compounds in a CAS ONLINE structure display. See ~~answer 1 RN 220141-43-5; answer 15 RN 220100-73-2; answer 27 RN 220100-57-2;~~ ~~u: 6, 110, 914, e61. 3-4,~~ and ~~answer 45 RN 220100-36-7 in WO 9903859~~ from a CAS ONLINE structure display. Phillips et al. disclose the instant claims when, in the instant claims R is hydrogen or C1-C4 alkyl; R1 is (CH₂)_nAr, ~~and CH₂CH=CHAr~~; R2 is absent; and n, A, and Ar are as defined.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The prior art discloses a broader genus than the instant claims.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to use the disclosure of Phillips et al. to prepare the instant compounds because of the species examples Phillips et al. which are included in the genus of the instant claims (see the CAS ONLINE structure display cited supra). Further, one of ordinary skill in the art would expect that compounds which are similar in structure to the compounds of Phillips et al. would have similar use in treating disorders involving reduced cholinergic function such as Alzheimer's disease.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation "A pharmaceutical composition", and the claim also recites "including a compound as defined in claim 1 in admixture with an inert pharmaceutically acceptable diluent or carrier" which is the narrower statement of the range/limitation.

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Claims 15-24 are hybrid claims. The claims contain two categories of inventions. Claim 15 is drawn to both a compound and its method of use. It is unclear whether Applicant intends to claim the compound or its use in therapy. Claim 16 is drawn to both a composition and a compound. It is unclear whether Applicant intends to claim a compound or a composition containing the compound. Claims 17-24 are drawn to both compositions and methods of use. It is unclear whether Applicant intends to claim a composition or its ability to treat various diseases. It is requested that each claim be written in the proper form wherein each claim consists of one category of invention.

Claim 43 recites the limitation "E is NHR". This limitation lacks antecedent basis in claim 43 because the claim is independent and the variable "R" is not defined therein.

Claims Objection

Claims 4, 5 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Celia Chang

Primary Examiner

Group 1600

Sonya Wright

June 10, 2002